UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Jane Doe, individually and as a representative of the classes, Plaintiff, **v.** Allergan, Inc. f/k/a Inamed Corporation, Allergan USA, Inc., Allergan plc, McGhan Medical Corporation, and Inamed Corporation, Defendants.	:	Case No. 2:19-cv-05911 **COMPLAINT – CLASS ACTION** JURY TRIAL DEMANDED

COMES NOW, Jane Doe ("Plaintiff"), on behalf of herself and the classes set forth below and states as follows upon personal knowledge as to her own experiences and on information and belief as to all other matters based on an investigation by counsel, against Allergan, Inc., a corporation formed under the laws of Delaware with a principal place of business located at 5 Giralda Farms, Dodge Dr, Madison, NJ 07940, Allergan USA, Inc., a corporation formed under the laws of Delaware with a principal place of business located at 5 Giralda Farms, Dodge Dr, Madison, NJ 07940, Allergan plc, a corporation formed under the laws of Ireland with a principal place of business located at 5 Giralda Farms, Dodge Dr, Madison, NJ 07940, as well as McGhan Medical Corporation, a company previously a part of Inamed Corporation, and Inamed Corporation, a company that Allergan purchased substantially all of as described further below.

NATURE OF THE ACTION

1. Defendant Allergan plc ("Allergan") manufactures and sells BIOCELL© saline-filled and silicone-filled breast implants and tissue expanders ("BIOCELL©"). On July 24, 2019, Allergan announced a worldwide recall of BIOCELL© after the U.S. Food and Drug Administration ("FDA") called for the action following new information that Allergan's

BIOCELL© implants were tied to a vast majority of cases of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL") not seen with other textured implants. Allergan announced that BIOCELL© would no longer be sold or distributed in any market.

2. BIA-ALCL is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread through the body. Even if an individual's risk of developing BIA-ALCL is considered low, this cancer is serious and can lead to death, especially if not treated promptly. BIA-ALCL can be treated with surgery to remove the implant and surrounding scar tissue, and in some patients, may also require treatment with chemotherapy and radiation treatment. The recommended diagnostic testing for BIA-ALCL is invasive. The Directions for Use ("DFU") for doctors provides in pertinent part: "When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule, and send for pathology tests to rule out ALCL." The symptoms of BIA-ALCL may occur well after the surgical incision has healed, often years after the implant placement.

3. In its July 24, 2019 announcement, the FDA stated that there are 573 cases of BIA-ALCL worldwide and that 33 people have died, a "significant increase" since the FDA's last update earlier in 2019 -- reflecting 116 new cases and 24 more deaths. The FDA stated that the risk of developing BIA-ALCL with Allergan BIOCELL© textured implants is about six times that of becoming ill with textured implants from other manufacturers available in the U.S. The FDA noted that of the 573 cases of BIA-ALCL, 481, or more than 80%, were attributed to Allergan implants, and of the 33 deaths caused by BIA-ALCL, 12 of the 13 patients for whom the implant manufacturer was known had an Allergan implant when they were diagnosed. Dr. Amy Abernethy, principal FDA deputy commissioner stated: "Based on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "Once the evidence

indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action."

4. The recalled BIOCELL© products are:

Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) approved under P990074. The following are the textured styles:

- Style 163: BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants
- Style 168: BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile)
- Style 363: BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection
- Style 468: BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants

Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants) approved under P020056. The following are the textured styles:

- Style 110: BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants
- Style 115: BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants
- Style 120: BIOCELL Textured Round High Projection Gel Filled Breast Implants
- Style TRL: Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TRLP: Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TRM: Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TRF: Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TRX: Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TCL: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants

- Style TCLP: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCM: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCF: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCX: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TSL: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSLP: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSM: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSF: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSX: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under P040046. The following are the textured styles:

- Style 410FM
- Style 410FF
- Style 410MM
- Style 410 MF
- Style 410 FL
- Style 410 ML
- Style 410 LL
- Style 410 LM
- Style 410 LF
- Style 410 FX
- Style 410 MX
- Style 410 LX

Allergan tissue expanders for the breast that have BIOCELL texturing originally cleared as:

- Natrelle 133 Plus Tissue Expander (K143354)
- Natrelle 133 Tissue Expander with Suture Tabs (K102806)

5. On July 30, 2019, Carrie Strom, Senior Vice President, U.S. Medical Aesthetics, Allergan plc, sent the following letter to "Allergan Plastic Surgery Customer[s]":

> Dear Allergan Plastic Surgery Customer,
>
> In follow-up to Allergan's voluntary recall of unused BIOCELL® products, we created the **BIOCELL® Replacement Warranty** for all patients currently implanted with BIOCELL® textured implants.
>
> **For patients in the U.S. who, as a result of the recall announcement on July 24, 2019, choose to replace their BIOCELL® textured devices with smooth devices in consultation with their plastic surgeon, Allergan will provide Allergan smooth device replacements for free.** The program will run for 24 months, until July 24, 2021, and will apply to revision surgeries on or after the date of the recall announcement, July 24, 2019.
>
> The decision to get a breast implant revision is a personal decision between patients and their plastic surgeons, and must be decided based on the appropriate discussion of benefits and risks. **As part of this program, Allergan will not provide surgical fee assistance to revision patients.** This decision is in-line with the FDA's recommendation not to remove textured implants or other types of breast implants in patients who have no symptoms of Breast Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL") due to the low risk of developing BIA-ALCL. Patients who decide to keep their BIOCELL® textured devices will continue to be covered under the NATRELLE® ConfidencePlus® warranty, which includes reimbursement for up to $1,000 in diagnostic fees and up to $7,500 in surgical fees related to diagnosing and treating BIA-ALCL.
>
> Some frequently asked questions about this policy are attached. You may initiate a replacement request under the BIOCELL® Replacement Warranty by talking with your Allergan Plastic Surgery Sales representative or by contacting the Allergan Product Surveillance team prior to surgery at 1-800-624-4261.
>
> Sincerely,
> Carrie Strom
> Senior Vice President, U.S. Medical Aesthetics
> Allergan plc

Allergan's decision as set forth in its July 30, 2019 letter not to provide surgical fee assistance for breast implant revision, but instead to provide only free smooth device replacements and limited reimbursement for diagnostic and surgical fees, is insufficient.

6. In violation of federal law requiring Allergan to report adverse events to the FDA, and in order to conceal from doctors and the public, the full extent of the risks of BIOCELL© products, Allergan submitted adverse event reports with incorrect manufacturer names, including "Santa Barbra" and "Costa Rica," instead of under the name "Allergan."

7. Allergan received a substantial benefit from selling thousands of the recalled BIOCELL© products from 2006 through July 24, 2019 at the expense of Plaintiff and the Class (as defined below) who are exposed to the risk of developing BIA-ALCL, a serious and deadly disease. Plaintiff thus brings this action individually and on behalf of others in the United States who have recalled BIOCELL© textured breast implants and tissue expanders to seek relief for damages caused by Defendants' conduct at their expense. Plaintiff and the Class will be forced to expend substantial sums for the removal of the recalled implants, surgical and diagnostic fees, and/or medical monitoring and invasive diagnostic procedures required as a result of their exposure to the risk of contracting BIA-ALCL. Plaintiff seeks relief individually and for the Class to remedy the harms from Defendants' sale of recalled BIOCELL© products to Plaintiff and the Class.

THE PARTIES

8. Plaintiff Jane Doe, identified as such to protect her privacy, is, and was at all times relevant to this action, a citizen of the State of New York. In approximately August 2015, Plaintiff Jane Doe was implanted with a BIOCELL© recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference number MX 410420. Plaintiff Jane Doe paid approximately $10,000.00 for the BIOCELL© product and the procedure. In

approximately August 2019, Plaintiff Jane Doe had the BIOCELL© recalled product explanted and paid approximately $6,000.00 for the explant procedure and replacement with non-recalled Smooth Shell Surface Natrelle Saline-Filled Breast Implants, Reference Number 68-420. Plaintiff Jane Doe would not have had the recalled BIOCELL© product implanted had she known prior to the procedure that implantation with BIOCELL© would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

9. Defendant Allergan plc is a publicly-traded corporation whose headquarters are in Dublin, Ireland. Allergan's administrative headquarters in the United States are located in the States of New Jersey and California.

10. Defendant Allergan, Inc., formerly known as Inamed Corporation ("Inamed"), and prior to that known as McGhan Medical Corporation ("McGhan"), is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

11. Defendant Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

12. Defendant McGhan Medical Corporation ("McGhan") previously served the North American aesthetic medicine and reconstructive surgery markets. McGhan developed, manufactured, and sold plastic and reconstructive surgery ("PRS") products (primarily saline-filled breast implants and tissue expanders). It sold primarily to plastic surgeons, dermatologists, cosmetic surgeons, and other medical practitioners in the United States and Canada. McGhan changed its name to Inamed Corporation ("Inamed") in 1986.

13. Defendant Inamed was a global surgical and medical device company engaged in the development, manufacturing, and marketing of products for the plastic and reconstructive surgery, aesthetic medicine, and obesity markets. Inamed sold a variety of lifestyle products, including breast implants for cosmetic augmentation and breast implants for reconstructive surgery following a mastectomy. In March 2006, Allergan purchased substantially all of Inamed including Inamed's outstanding common stock, as well as Inamed's wholly-owned subsidiary, McGhan.

14. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other, and reference to "Allergan," "Defendant" or "Defendants" herein refers to each and every Defendant individually and collectively.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which Plaintiff and some members of the Class are citizens of states different than Defendants, and the number of Class members exceeds one hundred. *See* 28 U.S.C. § 1332(d).

16. This Court has personal jurisdiction over Defendants because Defendants conduct substantial business in New York and within this District. Defendants have sufficient minimum contacts with New York and intentionally avail themselves of the consumers and markets within New York through the promotion and sale of their products, including now-recalled BIOCELL©. Plaintiff's purchase of now-recalled BIOCELL© product and her surgery implanting the now-recalled BIOCELL© product both occurred in New York and within this District.

17. Venue properly lies in this District pursuant to 28 U.S.C. § 1391 because a substantial part of the acts giving rise to Plaintiff's claims occurred in this District and because Defendants are subject to personal jurisdiction within this District.

FACTUAL ALLEGATIONS

I. Breast Implants and ALCL.

18. A breast implant is a prosthetic product used to change the size, shape, and contour of a woman's breast. There are three general types of breast implant products, defined by their filler material: saline solution, silicone gel, and composite filler. Breast implants are available in various sizes and can have either a smooth or textured shell.

19. Approximately 300,000 total breast implants are placed per year in the U.S. From 2000 to 2016, the number of breast augmentations in the United States rose 37%, and reconstructions after mastectomy rose 39%.

20. In 2011, a summary of published studies, evidence, and reports was published that identified 27 cases of ALCL, and concluded that there was an association between breast implants and ALCL. In January 2011, the FDA released a report on BIA-ALCL, listing as its primary finding the following: "[b]ased on the published case studies and epidemiological research, the FDA believes that there is a possible association between breast implants and ALCL." The FDA further noted that, while it was not prepared to associate a particular type of breast implant with BIA-ALCL, "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell."

21. The natural occurrence of ALCL is 1/300,000. However, the FDA recently cited to studies that place the estimated current risk of BIA-ALCL in women with textured implants to be between 1:3,817 and 1:30,000. This is consistent with risks reported in Europe. A December 2016

update from Australia's Therapeutic Goods Administration ("TGA") reported a risk of 1:1,000 to 1:10,000 for textured implants.

22. In March 2015, an analysis identified 173 cases of ALCL. That same month, the French National Cancer Institute announced, "There is a clearly established link between the occurrence of this disease and the presence of a breast implant."

23. On May 19, 2016, the World Health Organization ("WHO") gave the disease an official designation as "BIA-ALCL" and classified it as a distinct clinical entity, separate from other categories of ALCL.

24. In November 2016, Australia's TGA convened an expert advisory panel to discuss the association between breast implants and ALCL and provide ongoing advice.

25. On March 21, 2017, the FDA released a safety communication updating the current understanding of BIA-ALCL. In the Updated Safety Alert, the FDA recognized the WHO's designation that BIA-ALCL can occur after a patient receives breast implants, and stated that "[a]t this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."

26. In May 2017, a global analysis of forty governmental databases identified 363 cases of BIA-ALCL with 258 being reported to the FDA.

27. A September 2017 update from the FDA reported that the agency had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including nine deaths.

28. On May 9, 2018, Australia's TGA reported 72 cases of ALCL in Australian patients.

II. Allergan's Repeated Attempts to Conceal the Risks of ALCL Associated with its Breast Implants.

29. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). Upon enactment of the MDA, the FDA deemed saline-filled breast implants as Class II devices, to be reviewed through a premarket notification process. The devices could be publicly sold so long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. § 360e(d)(2). In 1988, in response to growing safety concerns, the FDA re-classified both saline-filled and silicone gel-filled breast implants as Class III devices requiring premarket approval ("PMA").

30. In April 1991, upon final publication of new regulations, the FDA began requiring breast implant manufacturers to obtain specific premarket approval by the FDA for any silicone gel-filled breast implants. Through its PMA process, the FDA engages in scientific evaluations of the safety and effectiveness of Class III medical devices. The FDA considers Class III devices to create the greatest risk to human safety, necessitating the implementation of special controls, including the requirement to obtain PMA under 21 U.S.C. § 360 prior to marketing the product to the public.

31. A PMA application must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement Application must provide:

a. Proposed indications for use;

b. Device description including the manufacturing process;

c. Any marketing history;

d. Summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk;

e. Each of the functional components or ingredients of the device;

f. Methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. Any other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should be reasonably known to the manufacturer from any source, including information derived from investigations other than those proposed in the application from commercial marketing experience.

32. Allergan's Natrelle® silicone-filled breast implants are Class III medical devices receiving pre-market approval by the FDA in November 2006.

33. As conditions of the 2006 approval, the FDA required Allergan to conduct six post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies for Allergan's Natrelle® Silicone-Filled breast implants included:

a. Core Post-Approval Studies (Core Studies) – To assess long-term clinical performance of breast implants in women that enrolled in studies to support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.

b. Large Post-Approval Studies (Large Studies) – To assess long-term outcomes and identify rare adverse events by enrolling more than 40,000 silicone gel-filled breast implant patients, following them for 10 years.

c. Device Failure Studies (Failure Studies) – To further characterize the modes and causes of failure of explanted devices over a 10-year period.

d. Focus Group Studies – To improve the format and content of the patient labeling.

e. Annual Physician Informed Decision Survey (Informed Decision Study) – To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.

f. Adjunct Studies – To provide performance and safety information about silicone gel-filled breast implants for the period when implants could only be used for reconstruction and replacement of existing implants.

34. The PMA provided that "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

35. After receiving premarket approval for a Class III device, manufacturers are subject to a continuous obligation to comply with Medical Device Reporting pursuant to 21 U.S.C. § 360i(a)(1) and 21 C.F.R. § 803.50(a). Significant to this action, manufacturers are required to file adverse event reports with the FDA.

36. The primary responsibility for timely and accurately communicating complete, accurate, and current safety and efficacy information related to medical devices, such as Allergan's Natrelle® Silicone-Filled breast implants, rests with the manufacturer.

37. This primary reporting obligation instills in the manufacturer a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report all relevant information, specifically but not limited to adverse events, to the FDA, the healthcare community, and consumers.

38. According to the FDA, the purpose of filing the reports is to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments.[1]

[1] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM (last visited October 18, 2019).

39. These reports can be accessed on the FDA's Manufacturer and User Facility Device Experience ("MAUDE"). Running a search on MAUDE as of the date of this Complaint generates approximately 300 BIA-ALCL cases and approximately 1,400 injury reports.

40. In order to conceal the true number of adverse event reports, Allergan reported adverse event reports with incorrect manufacturer names, including "Santa Barbra" and "Costa Rica," instead of under the name Allergan.[2] As a result, consumers, healthcare professionals, and the FDA were unable to detect trends in Allergan's products, depriving the market of the necessary information to make an informed decision about whether Allergan's products were safe and effective.

41. Equally as troubling, Allergan's practice was to "bury evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure" until 2017.[3] This was done through filing "Alternative Summary Reports" ("ASR") for multiple adverse event reports all at one time, instead of filing an adverse event report for each individual adverse event. The ASRs require less detail and are not publicly available through the MAUDE website.

42. In 2017, the FDA no longer permitted the filing of ASRs.[4] Prior to 2017, there were, on average, fewer than 200 breast implant injuries reported a year. In 2017, this number skyrocketed to 4,567 adverse events, and nearly doubled to 8,242 in the first half of 2018.

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[2] *See also* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=7521708 (last visited October 18, 2019) (listing "Costa Rica").

[3] *See* https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface (last visited October 18, 2019).

[4] *See* https://www.medtechdive.com/news/fda-ends-alternative-reporting-program-pledges-to-make-maude-user-friendly/557465/ (last visited October 18, 2019).

43. Due to Allergan's reporting practices, medical professionals and consumers relying on the public reports would be unable to draw an accurate conclusion about the safety of a particular medical device.

44. Indeed, Allergan reported a case of possible BIA-ALCL through a non-public ASR.[5]

45. Under state laws, including New York law which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

46. Time is of the essence when monitoring and reporting adverse events, especially those indicating an association between a medical product and breast cancer, ALCL and/or BIA-ALCL, as required by federal regulations, as well as by New York law.

47. Delayed reporting prevents the healthcare community and the public from timely learning of risks which inevitably play a part in their decision-making, including by both physicians and consumers, regarding treatments and procedures, and thereby exposes countless additional women to potential harm.

48. Allergan failed to report adverse events from the post-market approval studies commissioned as part of the implant's PMA approval that would have led to reports suggesting the devices' contribution to serious injury.

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[5] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=7521708 (last visited October 18, 2019) ("[A] possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (alcl), a type of non-hodgkin[]s lymphoma.").

49. Had Defendants not intentionally failed to comply with their clearly-established post-market surveillance obligations, Plaintiff and the Class would have decided against implantation, as there is reasonable assurance that information in adverse reports and similar disclosures to the FDA will reach those whose safety depends on their having it.

50. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to exercise reasonable care in adequately warning Plaintiff, Class members, and/or implanting medical professionals about the dangers of Allergan's Natrelle® Silicone-Filled breast implants, and about all adverse events of which Allergan became aware, and further, had a post-market duty to identify, monitor, and report all adverse events and all risks associated with the product.

51. Despite having knowledge and possession of evidence showing that the use of Allergan's Natrelle® Silicone-Filled breast implants was dangerous and likely to place consumers' health at serious risk, as detailed further below, Allergan refused or recklessly failed to identify, disclose, and warn of the health hazards and risks associated with the product, and about all adverse events that were known to Allergan.

52. Pursuant to 21 C.F.R. § 814.39(d)(1)-(2), Allergan was permitted to unilaterally make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association" in order to "reflect newly acquired information."

53. From 2006 through the date of Plaintiff's implant, Allergan continually acquired new information regarding the strong association between its Natrelle® and BIOCELL© implants and the development of BIA-ALCL; an association that was significantly higher than any other textured breast implant.

54. Based on the newly acquired information, Allergan had the right to unilaterally make changes to the directions for use ("DFU") for its Natrelle® and BIOCELL© implants to add or strengthen the warnings about the causal association between the product and the development of BIA-ALCL.

55. Rather than exercise its right to unilaterally strengthen the information about the link between its product and BIA-ALCL, Allergan instead actively concealed its acquired knowledge of the causal link through its manipulation of adverse event reports and other public reports as described above.

56. Additionally, under applicable state laws, which do not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to revise its product labeling after becoming aware of otherwise undisclosed dangers in its Natrelle® and BIOCELL© breast implant products. Allergan refused and recklessly and intentionally failed to do so.

57. Under applicable state laws, which do not impose duties or requirements materially different from those imposed by federal law, Allergan was required at all material times to promptly report any information suggesting that one of its products may have contributed to a serious injury, or had malfunctioned, and the malfunction would be likely to contribute to a serious injury if it were to recur.

58. Allergan's insufficient follow-up rates and inadequate data, as detailed above, establish and confirm Allergan's reckless and intentional disregard for the safety of hundreds of thousands of women in the United States.

59. Each of the above-cited deficiencies in Allergan's post-market compliance, including those described above, was a "failure to comply with any post-approval requirement"

and each constituted a ground for withdrawal of the PMA. Defendants' conduct violated Defendants' duties under the law.

60. Notwithstanding Allergan's failures to comply with post-approval requirements, including the failures described above, Allergan continued to commercially distribute its Natrelle® and BIOCELL© breast implants. As expressly provided in the PMA, such distribution was a violation of federal law.

61. Had Allergan substantially complied with the PMA, rather than flagrantly, recklessly, and intentionally underperforming the post-approval requirements as alleged above, Allergan's disclosures would have led to much wider knowledge of the risks associated with Allergan's products. In addition, Allergan's physician and patient labeling would have materially changed over time, and patients including Plaintiff, and medical providers including Plaintiff's physician, would not have purchased or implanted Allergan's products.

CLASS ALLEGATIONS

62. Plaintiff brings this action individually and as a class action, pursuant to FED. R. CIV. P. 23(a), 23(b)(2) and/or 23(b)(3). Specifically, the Class consists of the following:

> **Nationwide Class:** All persons in the United States who have been implanted with BIOCELL© saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA.

Or, in the alternative,

> **New York Subclass:** All persons in New York who have been implanted with BIOCELL© saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA.

63. Together, the National Class and the New York Subclass shall be collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers and directors; and the Judge(s) assigned to this case.

64. Plaintiff reserves the right to redefine the Class prior to class certification.

65. The rights of each member of the Class were violated in a similar fashion based upon Defendants' uniform actions.

66. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. Plaintiff is informed and believes that the proposed Class contains at least thousands of individuals in whom recalled BIOCELL© products were implanted from 2006 through July 24, 2019. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiff at this time, but the Class members are readily ascertainable and can be identified by Defendants' records.

b. Existence and Predominance of Commons Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

i. Whether Defendants were unjustly enriched by the sale of BIOCELL© recalled products;

ii. Whether Defendants were negligent in selling BIOCELL© recalled products;

iii. Whether Defendants failed to warn consumers regarding the risks of the BIOCELL© recalled products;

iv. Whether Defendants violated federal standards and requirements for the marketing, warning, and reporting of the recalled BIOCELL© products;

v. Whether Defendants breached implied warranties connected with the recalled BIOCELL© products;

vi. Whether Defendants' practices constitute unfair or deceptive acts or practices under New York General Business Law ("GBL") § 349;

vii. The appropriate nature of class-wide equitable relief; and

viii. The appropriate measurement of restitution and/or measure of damages to Plaintiff and members of the Class.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiff's claims are typical of the claims of all members of the Class who were implanted with recalled BIOCELL© products.

d. Adequacy: Plaintiff is an adequate representative of the Class because her interests do not conflict with the interests of the Class that she seeks to represent; she has retained counsel competent and highly experienced in complex class action litigation and she intends to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiff and her counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system

could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

CAUSES OF ACTION

COUNT I
STRICT LIABILITY-FAILURE TO WARN
On Behalf of the Class

67. Plaintiff and the Class incorporate by reference all preceding paragraphs.

68. Defendants had a duty to warn Plaintiff and the Class members regarding the true risks associated with BIOCELL© implants through submitting accurate adverse event reports as well as amending its warnings contained within the product DFUs.

69. In and around the date of Plaintiff's implant surgery, Allergan's Directions for Use ("DFU") for the Natrelle 410 implants failed to relay Allergan's actual knowledge of the clear causal connection between its BIOCELL© implants and BIA-ALCL, an association that was significantly greater than the risk posed by other manufacturers' breast implants.

70. Beginning in 2006, Defendants continually acquired new information regarding the true risks with BIOCELL© implants and their clear causal connection to BIA-ALCL but failed to warn Plaintiff, Class members, and their physicians by not submitting accurate adverse action reports and failing to unilaterally strengthen their warnings. Defendants' failure to submit accurate adverse event reports made their warning inadequate and the implants defective.

71. Pursuant to 21 C.F.R. § 814.39(d)(1)-(2), Allergan was permitted to unilaterally make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or

information about an adverse reaction for which there is reasonable evidence of a causal association" in order to "reflect newly acquired information."

72. Despite Allergan's ability to unilaterally strengthen its warning regarding the newly acquired knowledge of the link between BIOCELL© implants and BIA-ALCL, it instead chose to actively conceal this knowledge and causal association through its manipulation of adverse event reports and other reporting data.

73. Had Allergan properly reported those adverse events, the FDA would have required it to add warnings to the label or otherwise disseminate the additional adverse event information to the implanting doctors at a minimum, and would have required the BIOCELL© implants to be recalled sooner. This is confirmed by the FDA's 2019 request that BIOCELL© implants be recalled and removed from the market once Allergan disclosed the true causal association between the implants and BIA-ALCL.

74. Moreover, if implanting physicians had been provided with the appropriate warnings regarding the causal connection between BIOCELL© implants and BIA-ALCL, they would have chosen to use an alternative product that did not present such a high risk of BIA-ALCL.

75. Defendants' breach of their duty to warn have caused Plaintiff and Class members damages in the form of surgical costs of removal of the products and/or the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products.

76. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the BIOCELL© implants had they known that they would be exposed to the risk of developing BIA-ALCL.

77. This defect proximately caused Plaintiff's injuries. When the BIOCELL© implants are surgically placed in the body, the textured surface disrupts the body's normal healing process and was thought to result in scar tissue that was less firm than that produced by smooth-walled implants. However, it is believed that the BIOCELL© implants' textured surface creates an implant-induced chronic inflammation that results in injury to the structure of cells in and around the implant.[6] Plaintiff and Class members have sustained such cellular damage as a result of the BIOCELL© implants, and a currently unknown number of such Class members will go on to develop BIA-ALCL as a result of this damage and neoplastic transformation.

78. Plaintiff and Class members have also been injured by undergoing a surgery and implantation of a medical device and invasive diagnostic procedures, and in some cases an explant procedure, that they would not have had done if they were made aware of the true risks posed by the BIOCELL© implants.

79. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT II
NEGLIGENCE
On Behalf of the Class

80. Plaintiff and the Class incorporate by reference all preceding paragraphs.

81. Defendants owed Plaintiff and Class Members a duty of care and to warn of any risks associated with the recalled BIOCELL© implants. Defendants knew or should have known of the true risks with BIOCELL© implants but failed to warn Plaintiff, Class members, and their physicians by not submitting accurate adverse action reports. By submitting misleading adverse

[6] George EV, Pharm J, Houston C, *et al.*, Breast implant-associated ALK-negative anaplastic large cell lymphoma: a case report and discussion of possible pathogenesis. Int J Clin Exp Pathol. 2013;6; Bizjak M, Selmi C, Praprotnik S, et al., Silicone implants and lymphoma: the role of inflammation. J Autoimmun. 2015;65:64–73.

event reports, and concealing the risks associated with the recalled BIOCELL© implants, Defendants negligently violated their duty of care to Plaintiff and Class Members and their doctors.

82. Defendants' breach of duty caused Plaintiff and Class members damages in the form of surgical costs of removal of the products and/or the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products.

83. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the BIOCELL© implants had they known that they would be exposed to the risk of developing BIA-ALCL.

84. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT III
NEGLIGENT RECALL
On Behalf of the Class

92. Plaintiff and the Class incorporate by reference all preceding paragraphs.

93. On July 24, 2019, the FDA requested that Allergan recall its BIOCELL products in the United States. That same day, Allergan voluntarily issued a worldwide recall of BIOCELL products.

94. In issuing a voluntary recall, Allergan assumed duties to Plaintiff and the Class to exercise reasonable care in issuing and implementing the recall.

95. Allergan breached its duties by failing to adequately warn Plaintiff and the Class of the dangers associated with the use of the recalled BIOCELL products and by refusing to pay for the surgical removal of Plaintiff's and Class members' implants notwithstanding the clear connection between the recalled BIOCELL products and BIA-ALCL and the continuing risk the implants pose to Plaintiff's and Class members' health.

86.96. As a direct result of Allergan's breach of duty, Plaintiff and the Class have suffered harm in an amount to be determined at trial.

COUNT IV
UNJUST ENRICHMENT
On Behalf of the Class (In the Alternative)

85. Plaintiff and the Class incorporate by reference all preceding paragraphs.

86. Plaintiff and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing recalled BIOCELL© implants from 2006 through July 24, 2019. Plaintiff and Class members would not have purchased, chosen and/or paid for all or part of BIOCELL© had they known that they would be exposed to the risk of developing BIA-ALCL, while Defendants refuse to compensate them for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products. Under these circumstances, it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiff and the Class.

87. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiff and the Class members who endure being exposed to the risk of developing a serious and deadly disease.

88. Defendants' retention of the benefit conferred upon them by Plaintiff and the Class would be unjust and inequitable.

89. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT V
MEDICAL MONITORING
On Behalf of the Class

90. Plaintiff and the Class incorporate by reference all preceding paragraphs.

91. Due to Defendants' actions and inactions in violation of federal law, medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of BIA-ALCL.

92. Plaintiff and the Class are thus entitled to have Defendants pay for the costs of ongoing medical monitoring.

COUNT VI
BREACH OF THE IMPLIED WARRANTY
OF MERCHANTABILITY
On Behalf of the Class

93. Plaintiff and the Class incorporate by reference all preceding paragraphs.

94. By operations of law, Defendants, as manufacturer of the recalled BIOCELL products and as the provider of a limited warranty for the products, impliedly warranted to Plaintiff and the Class that the implants were of merchantable quality and safe for their ordinary and intended use in the human body.

95. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the recalled BIOCELL products. At the point of sale, the recalled BIOCELL products —while appearing normal—contained latent flaws rendering them unsuitable and unsafe for use in the human body.

96. Had Plaintiff and the Class known the recalled BIOCELL products are unsafe for use in the human body, they would not have purchased them and had them implanted.

97. Defendants have refused to provide appropriate warranty relief notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiff and the Class reasonably expected, at the time of purchase, that their implants would not present a substantial risk of bodily harm.

98. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff and the class have sustained damages in an amount to be determined at trial.

COUNT VII
N.Y. GEN. BUS. LAW § 349
On Behalf of the New York Subclass

99. Plaintiff and the New York Subclass incorporate by reference all preceding paragraphs.

100. Plaintiff brings this cause of action on behalf of herself and on behalf of the members of the New York Subclass.

101. Plaintiff and the New York Subclass Members are "persons" within the meaning of New York General Business Law ("New York GBL"). N.Y. GEN. BUS. LAW § 349(h).

102. Defendants are a "person," "firm," "corporation," or "association" within the meaning of N.Y. GEN. BUS. LAW § 349.

103. New York's General Business Law § 349 makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. GEN. BUS. LAW § 349. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts or practices" within the meaning of the New York GBL. All of Defendants' deceptive acts and practices, which were intended to mislead consumers in a material way in the process of purchasing BIOCELL© implants, constitute conduct directed at consumers and "consumer-oriented." Further, Plaintiff and the New York Subclass Members suffered injury as a result of the deceptive acts or practice.

104. Defendants' actions, as set forth above, occurred in the conduct of business, trade or commerce.

105. Defendants participated in unfair or deceptive trade practices that violated the New York GBL as described below and alleged throughout the Complaint. By concealing the true risks of the BIOCELL© implants and failing to comply with federal law, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale of the BIOCELL© implants. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the BIOCELL© implants in the course of their business.

106. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the BIOCELL© implants.

107. Defendants' unfair and deceptive acts or practices occurred repeatedly in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, imposed a serious safety risk on the public, and were contrary to the public policy of New York which aims to protect consumers.

108. Defendants knew that the risks inherent in the BIOCELL© implants made them not suitable for their intended use.

109. Defendants knew or should have known that their conduct violated the New York GBL.

110. Had Plaintiff and the New York Subclass Members known the truth about the BIOCELL© implants, they would not have purchased and implanted the BIOCELL© implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

111. Defendants owed Plaintiff and the New York Subclass Members a duty to disclose the truth about the BIOCELL© implants because Defendants: (a) possessed exclusive, specific and

superior knowledge of the true risks of the BIOCELL© implants; (b) intentionally concealed the foregoing from Plaintiff and the New York Subclass Members; and/or (c) made incomplete representations regarding the BIOCELL© implants, while purposefully withholding material facts from Plaintiff and the New York Subclass Members that contradicted these representations.

112. Plaintiff and the New York Subclass Members suffered injury in fact to a legally protected interest. As a direct and proximate result of Defendants' conduct, Plaintiff and the New York Subclass Members were harmed and suffered actual damages.

113. Defendants' violations present a continuing risk to Plaintiff and the New York Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

114. Pursuant to N.Y. GEN. BUS. LAW § 349(h), Plaintiff and the New York Subclass Members seek actual damages or $50, whichever is greater, in addition to discretionary three times actual damages up to $1,000 for Defendants' willful and knowing violation of N.Y. GEN. BUS. LAW § 349. Plaintiff and the New York Subclass Members members also seek attorneys' fees, an order enjoining Defendants' deceptive conduct, and any other just and proper relief available under the New York GBL.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests, individually and on behalf of the Class, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the Nationwide Class and New York Subclass defined above, and designate Plaintiff as the class representative and Plaintiff's counsel as counsel for the Nationwide Class and New York Subclass;

B. award equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for Class Members, restitution, and disgorgement of profits;

C. award all actual, general, special, incidental, punitive, and consequential damages to which Plaintiff and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

E. award reasonable attorneys' fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

JURY DEMAND

Plaintiff and the Class demand a trial by jury on all issues so triable.

Dated: October 18, 2019

/s/ Russell D. Paul

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